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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,931	11/08/2004	Armin Studer	8932-1171-999	2919
69095 7590 11/26/2007 STROOCK & STROOCK & LAVAN, LLP 180 MAIDEN LANE NEW YORK, NY 10038			EXAMINER STEWART, ALVIN J	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 11/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,931	Applicant(s) STUDER, ARMIN	
	Examiner Alvin J. Stewart	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/01/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments with respect to claims 20-55 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner believes that the previous rejection still reads on a single integral member, a width, a length and a longitudinal axis and still reads on a distal exterior end and a distal interior end (see below).

Regarding the new limitations "a distal exterior end and distal interior end" the Examiner wants to point out that two ends cannot be named "distal". If one of the ends is farther from the delivery system it can be called "distal" but if the other end is closer to the delivery system, that end should be called "proximal" in order to avoid confusion. Therefore, it should be written as follow: "a proximal exterior end and distal interior end".

The Examiner interpreted the distal exterior end as the section represented by element 5 in Figure 1 and the Examiner interpreted the distal interior end as the section represented by element 2 in Figure 2. The Examiner is interpreting the distal exterior end and the distal interior end as areas on the implant and is not interpreting the claims as the distal free end of the implant. Therefore, in order to overcome the rejection the Applicant's representative should say the following: "a proximal exterior free end and a distal interior free end". If the Applicant's representative enters the above limitations, the Examiner still believes that a 103(a) rejection can be made.

The Applicant's representative must enter the above limitations in the specification in order to avoid lack of antecedent basis in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-26 and 31, 33-46, 49-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Husson et al US Patent 5,919,235.

Husson et al discloses an intervertebral implant (S) comprising a longitudinal flexible body that can be wound in a spiral shape (see Figs. 3 and 2) with a first distal exterior end (5), a second distal interior end (1), a longitudinal axis and a cross section of the object which is orthogonal towards the central axis is reduced in size towards the second interior end.

The examiner interpreted the distal exterior end as an area close to section 5 (see Figure 1) and the distal interior end as an area close to section 2. Therefore, the intermediate point is wider than the two distal ends (see Fig. 1).

Regarding claim 26, see Figs. 1 and 2.

Regarding claims 33-34, see col. 5, lines 22-27.

Regarding claim 35, see Fig. 1.

Regarding claims 24 and 36, see Fig. 2A.

Regarding claims 31, 37 and 49, a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable

Art Unit: 3738

depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. *In re Klug*, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. *In re Hirao et al.*, 535 F2d 67, 190 U.S.P.Q. 15, *see footnote 3* (CCPA 1976).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-30, 32, 47, 48, 52, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husson et al US Patent 5,919,235.

Husson et al discloses the invention substantially as claimed. However, Husson et al does not disclose a gap having a width of no more than about 1.0 mm wide, a surface area between about 250 mm² and 750 mm², the member made of hydrogel, a recess and an injection point in the recess.

It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the width, the surface area and the material property of the Husson et al reference because Applicant has not disclosed that by having the gap width, surface area and the hydrogel material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform

Art Unit: 3738

equally well with the gap, the surface area and the material disclosed in the Husson et al reference because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the Husson et al reference to obtain the invention as specified in claims 27-30.

Regarding claims 32 and 52, At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to add a recess with an injection point at the upper surface near the interior end of the implant because Applicant has not disclosed that by having a recess with an injection point provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with flat surface because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify Husson et al reference to obtain the invention as specified in claims 32 and 52.

Regarding claims 54 and 55, At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to add indentations and have a cross section width smaller than the inner layers because Applicant has not disclosed that by having a cross section width smaller than the inner layers and an indentation provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with above mentioned limitations because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify Husson et al reference to obtain the invention as specified in claims 54 and 55.

Response to Arguments

Applicant's arguments filed 04/20/07 have been fully considered but they are not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3774

November 15, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER